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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/554,835 | 07/05/2000 | HANS PROPPERT | HARMSEN002 | 8966 |

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| EXAMINER | |
|---|---|
| MARX, IRENE | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1651 | |

DATE MAILED: 11/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Applicati n No. | Applicant(s) | |
|---|---|---|---|
| | 09/554,835 | PROPPERT, HANS | |
| | Examiner | Art Unit | |
| | Irene Marx | 1651 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *06 October 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☐ Claim(s) *3,8,13-17 and 19-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *3,8,13-17 and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/6/03 has been entered.

Claims 3, 8, 13-17 and 19-21 are being examined on the merits

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 8, 13-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the designation "DSX 6601" for an *E. coli* strain.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 8, 13-17 and 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is vague and indefinite in the incorrect designation "DSX 6601". To advance prosecution, it will be assumed that applicants intend DSM 6601.

Claims 15 and 16 are incomplete as depending on a cancelled claim.

Claim 8 is vague and indefinite in that the time period encompassed by "at least about 10 days" is unclear, even when reading the claim in light of the specification.

Claims 3 and 17 are vague and indefinite in that the "therapeutically effective amount" required to "prevent" diarrhea or to "prevent" intestinal colonization in all subjects for all conditions is not set forth with sufficient particularity in the as filed written disclosure. The time period of "preventing" is also unclear. Is it during administration?

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless - -
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

***Claim Rejections - 35 USC § 102***

Claims 3, 8, 17 and 19 remain/are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hockertz [AT] or Lodinova-Zadnikova et al. [AR] or under 35 U.S.C. 102 (a) as being clearly anticipated by DE 196 37 936 [AL] for the reasons as stated in the last Office action and the further reasons below.

The claims are directed to preventing or treating diarrhea in a mammal, including diarrhea mediated by pathogenic fungi, comprising administering viable *E. coli* DSM 6601.

***Response to Arguments***

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants arguments that the Hockertz [AT] reference does not contemplate prophylactic or therapeutic effects on the strain on fungi other than *Candida* is not dispositive of the issues of anticipation. At least the steps, dosage, mode of administration, and patient are the same. With respect to biochemical pathways, no evidence has been provided to substantiate the allegations made regarding differences. Regarding, Lodinova-Zadnikova et al. applicants' arguments that competitive exclusion would apply to bacteria and not the fungi is not understood. The basis for this contention is not set forth.

In response to applicants' conclusion that nystatin is the only effective component in the preparation of the German patent, and that DSM 6601 is not administered alone, it is noted that the present invention is directed to a method comprising the administration of DSM 6601; there is no proviso that this must be the sole active ingredient. Also, that the strain is not disclosed as a fungicidal means is irrelevant, since it clearly at least boosts the effects of nystatin. In this regard it is noted that claim 17 is specifically directed to preventing intestinal colonization of pathogenic fungi. There is nothing in the reference to teach away from the administration of DSM 6601 in a therapeutically effective amount, as instantly claimed.

Applicants argue that based on the examiner's rationale, administration of DSM 6601 would inherently teach treating all diseases and that is contrary to case law. See *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993). The board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of *P. cepacia*. A US patent to Dart disclosed inoculation using *P. cepacia* bacteria for protecing the plant from fungal disease. Dart was silent with regard to nematode inhibition, but the Board concluded that nematode inhibition was an inherent property of the bacteria, and therefore of the method as disclosed by Dart.

While discovery of the biological mechanism behind the administration of a known bioactive compound is clearly publishable in a peer-review journal, the criteria for patenting claims are distinct from publication criteria. For example, if the active step of the method is the same and the subject is the same, then the claimed method can be anticipated or made obvious by the prior art, even if the prior art does not recognize or appreciate this mechanism as long as the compound administered, dosage, mode of administration, subject, etc. are the same as in the method disclosed in the prior art.

If this were not so, one patent might issue with a one step claim of administering the a compound to a subject in order to empirically treat a specific disease which is result of a contemporaneously unknown, disordered mechanism or pathway; and, then upon later discovery of the mechanism of the disorder, another patent could issue with a one step claim directed to the administration of the same compound to the same subject in order to modulate the specifically disordered mechanism or pathway. This would lead to multiple patents with essentially the same invention being patented, merely being couched in different words.

In re Cruciferous Sprout Litigation, Brassica_v_Sunrise., 64 USPQ2d 1202 (CA FC 2002), the Federal Circuit upheld a decision that patents owned by Johns Hopkins University and licensed to Brassica Protection Products, Inc. are invalid for anticipation by the prior art. The patents are for methods of growing and eating certain sprouts to reduce the level of carcinogens in animals, thereby reducing the risk of developing cancer. Prior art references disclose growing and eating those specific sprouts. The Federal Circuit cited authority for the rule that, "a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it." The court said, "While Brassica may have recognized something quite interesting about those sprouts, it simply has not invented anything new."

It is also of interest to emphasize that the written disclosure acknowledges that the effectiveness of the strain *E. coli* DSM 6601 depends at least to some extent on competitive exclusion. In addition, it is stated that the strain acts by increasing the body's endogenous defense mechanisms by immuno-stimulation (Specification, page 6, paragraph 3).

Therefore the rejection is deemed proper and it is adhered to.

***Claim Rejections - 35 USC § 103***

Claims 3, 8, 13-17 and 19-21 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over by Hockertz [AT] taken with Lodinova-Zadnikova et al. [AR] and DE 196 37 936 [AL] for the reasons as stated in the last Office action and the further reasons below.

Applicants argue that the problem to be solved is to combat effectively diarrhea caused by pathogenic fungi in mammals. Yet, while claim 3 and claims dependent thereon are directed to the prevention or treatment of diarrhea, claim 17 and claims dependent thereon the directed to the prevention or treatment of intestinal colonization of pathogenic fungi. There is no clear

between applicants' arguments and the claims as written. "Prevent" cannot be equated with "combat".

Applicants argue the benefits of the invention for suckling calves. However, the claims are not directed to the results touted described at page 10, lines 5-8 of the specification. Moreover, the results are unclear in the blank at page 9, line 11. No new matter may be added.

There is no clear indication of the dosage administered to obtain the touted results.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is 703-308-2922. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0926.

Irene Marx
Primary Examiner
Art Unit 1651